IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Art Unit: 1643
CLASSEN, John B.	Examiner: BRUMBACK, B.
Serial No.: 08/591,6[illegible]	Washington, D.C.
Filed: February 12, 1996	June 14, 1999
For: METHOD AND COMPOSITION FOR AN EARLY VACCINE...	Docket No.: CLASSEN=1A

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REQUEST FOR WITHDRAWAL OF FINALITY AND/OR VACATING OF LAST ACTION

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

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9-22-99

On May 4, 1999, the PTO mailed a final rejection in the above-identified case.

1. Applicant requests that finality be withdrawn on the ground that it was prematurely imposed. Finality is improper when the Examiner introduces a new ground of rejection that is neither "necessitated by applicant's amendment of the claims" nor based on a 1.97(c) IDS.

1.1. In section 4(a) of the office action, the Examiner states

> Applicant argues that the specification is enabled for the broad scope of the claims because anthrax, plague and DT were shown to favorably affect diabetes and further argues that anthrax and DPT are very different. Applicant, however, does not elucidate what the significant differences are between anthrax and DPT (the examiner has assumed that "DT" is diphtheria/tetanus and that "DPT" is diphtheria/pertussis/tetanus). What the disclosure has shown is a reduction in the incidence of diabetes in a mouse model by administration of one or more of five bacterial immunogens (Bacillus anthracis, Yersinia pestis, Corynebacterium diphtheriae, Bordetella pertussis, and Clostridium tetani). This effect appears to be amplified when two or more of these

> antigens are administered together. The immunogens as claimed include a myriad of different viral antigens, as well as bacterial antigens. Applicant has not demonstrated the same effect for viral immunogens absent bacterial proteins and lipopolysaccharides that has been demonstrated for the described bacterial antigens. (emphasis added)

In effect, the Examiner is making a "scope" rejection, arguing that it is improper for applicant to extrapolate from bacterial immunogens (anthrax, plague, diphtheria, pertussis tetanus) to viral immunogens. This is a new ground of rejection. While the prior action did refer to viruses, that was in the context of the "prevention of a wide variety of viral conditions" (page 4, lines 18-20). In the new rejection, the issue is the ability of the viral immunogen to reduce the incidence or severity of a chronic immune-mediated disorder, not to prevent a viral infection.

This new rejection was not necessitated by the amendment. The originally examined main claims all recited "immunogens" in a manner which did not exclude viral immunogens, and several dependent claims specifically recited one or more viral immunogens, see, e.g., claims 17 and 30.

It is clear that finality was improperly imposed.

1.2. Another new ground of rejection is stated in section 4(b), first six lines. Here, the Examiner makes a "scope" rejection arguing that it was improper for Applicant to extrapolate from epidemiological data for BCG, which contains heat shock protein, to other therapies which do not involve administration of a heat shock protein.

The initially examined claims were not limited to BCG, or other vaccines that contain HSP or other tolerogens (by way of aside, Applicant distinguishes tolerogens from immunogens).

1.3. A third new ground of rejection may be stated in section 4(i). While the Examiner previously challenged the extrapolation from rodents to humans, the Examiner has for the first time raised the issue of "the differences in maturation

rates between rodents and humans" as they relate to the proper timing of the administration. Since this puts into question the operability in humans of the claimed maximum age for the initial administration, which was not challenged previously, it seems only equitable to treat this as a new ground of rejection.

The "42 days" limitation was in the previously examined claims.

1.4. In section 5(d), the Examiner argues that "immunogen other than BCG" is indefinite. While the prior rejection challenged that phrase, it was on the ground that "other than BCG" was not a positive limitation. The Examiner now argues that "immunogens" per se is indefinite. That is a new ground of rejection.

2. 37 CFR §1.104(b) generally requires that "the examiner's action will be complete as to all matters". If it is not complete, that is grounds for vacating the prior action and requiring the examiner to issue a new and complete action (or, alternatively, issuing a supplemental action and resetting the period for response).

With regard to the prior art rejection in the case, the Examiner fails at pp. 9-10 to address the patents cited on pp. 13-14, or the policy arguments as pp. 14-16 of the last amendment. Hence, the action is incomplete.

Respectfully submitted,

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